K 111814

Reliance Orthodontic Products, Inc.
Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

SEP 14 2011

Section 8.0 **510 (k) Summary**

Note: This summary is provided in accordance with 21CFR807.92 (c).

510 (k) Owners Name:	Reliance Orthodontic Products, Inc. Paul Gange, President
Address:	1540 West Thorndale Avenue Itasca, Il 60143 USA
Phone Number:	630-773-4009
Fax Number:	630-250-7704
Contact Person:	Paula Wendland, Regulatory Affairs Manager (Preparer)

Date 510 (k) Summary was Prepared: June 16, 2011

Medical Device Name:

- Trade names - Light Bond™ and Pad Lock®
- Common name –Orthodontic Bracket Adhesives
- Classification name – Bracket Adhesive Resin and Tooth Conditioner (21CFR872.3750, Product Code DYH, Class II Device)

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED (PREDICATE DEVICE) [807.92(a) (3)]: QUICK CURE, K001048, approved 4/27/00.

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8.1 DESCRIPTION OF THE APPLICANTS DEVICE:

Light Bond and Pad Lock are light cure, orthodontic bracket adhesives available in a variety of viscosities for bonding to metal, ceramic and composite surfaces. Both Light Bond and Pad Lock are available in fluoride and non-fluoride formulas and come in syringe style or tip dispensing.
In addition, Pad Lock fluoresces to ease clean-up of flash for the user.

8.2 INTENDED USE AND POPULATION:

Light Bond adhesives are intended for use as a light cure bracket and lingual retainer adhesive.

Pad Lock adhesives are intended for use as a light cure bracket adhesive.

8.3 PREDICATE DEVICE:

Reliance Orthodontic Products, Inc. Quick Cure™, 510(k) submission (K001048) dated 04/28/2000.

8.4 TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics of Light Bond ™, Pad Lock and Quick Cure™:

Property	Light Bond™	Pad Lock®	Quick Cure™
Intended Use	**Light Cure Orthodontic bracket adhesive Containing Fluoride**	**Light Cure Orthodontic Bracket Adhesive Containing Fluoride**	**Light Cure adhesive for bonding Orthodontic brackets Containing Fluoride**
Mechanical / Physical Properties	**Syringe or Tip Delivery**	**Syringe or Tip Delivery**	**Syringe or Tip Delivery**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Paula Wendland, ASQ CQE
Regulatory Affairs Manager
Reliance Orthodontic Products, Incorporated
1540 West Thorndale Avenue
Itasca, Illinois 60143

SEP 14 2011

Re: K111814
Trade/Device Name: Light Bond™ and Pad Lock®
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: August 22, 2011
Received: August 24, 2011

Dear Ms. Wendland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111814

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3.2 Indications for Use Statement:

510 (k) Number (if known): K111814

Device Name: Light Bond™ and Pad Lock®

Indications for Use:

Light Bond is intended for use as an orthodontic bracket adhesive.

Pad Lock® is intended for use as a fluorescing, light cure Orthodontic Bracket Adhesive.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111814